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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,736	03/30/2004	Michael E. McClurken	TLK023CON	8083

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GROSSMAN, TUCKER, PERREAULT & PFLEGER, PLLC  
55 SOUTH COMMERICAL STREET  
MANCHESTER, NH 03101

EXAMINER
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ROANE, AARON F

ART UNIT	PAPER NUMBER
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3769

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07/12/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,736	<b>Applicant(s)</b> MCCLURKEN ET AL.	
	<b>Examiner</b> AARON ROANE	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 40-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 40-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/22/2010 and 02/17/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 14-26, 40-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent 6,149,620) in view of Eggers et al. (U.S. Patent 5,873,855).

Regarding claim 1, Baker et al. disclose an electrosurgical device to treat tissue in a presence of radio frequency power (see for example col. 7, lines 9-14) and a fluid (see for example 450, i.e. saline) provided simultaneously from a distal portion of the device, the device having a proximal end and a distal end, the device comprising: a handle (204 and alternate/equivalent counterparts in other embodiments); a shaft (100 and alternate/equivalent counterparts in other embodiments) extending from the handle, the shaft supporting an electrode (distal portion of array 504) in rigid relation (see for example col. 5, lines 12-17, col. 13, lines 1-17, col. 22, lines 11-29, col. 25, lines 4-22) to the handle and having a distal end; a fluid passage (554 and/or 557) being connectable to a fluid source of the fluid (421 and alternate/equivalent counterparts in other embodiments); the electrode having an electrode surface, at least a portion of the electrode extending distally beyond the distal end of the shaft; and at least one fluid outlet

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opening (distal openings of 554 and/or 557) in fluid communication with the fluid passage. Baker et al. fail to disclose the electrode is an electrically conductive cone shaped portion having a circular portion that narrows towards the distal of the device. Eggers et al. disclose a device similar to that of Baker et al. and teach an embodiment wherein “the distal of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel,” see col. 19:4-24 and figure 6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Baker et al., as taught by Eggers et al., to provide an embodiment wherein “the distal of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe

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through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel.”

Regarding claim 2, Baker et al. further disclose the at least one fluid outlet opening is arranged to provide the fluid from the fluid source to the electrode, see figures 20 and 27A-27C.

Regarding claim 3, Baker et al. further disclose at least a portion of the electrode surface has a contact angle with the fluid from the fluid source thereon of less than 90 degrees, see figures 27A-27C.

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Regarding claims 4 and 5, Baker et al. further disclose the at least one fluid outlet opening (opening of 557) located at the distal end of the shaft is located between a portion of the electrode contained within the shaft and the distal end of the shaft, see figure 27C.

Regarding claims 6-9, Baker et al. disclose the claimed invention, see distal portion/surface of 104 and distal portion/edge of 518 in figure 27C.

Regarding claims 10-12, Baker et al. disclose the claimed invention see col. 30-31 and figure 27C.

Regarding claims 14-17, Baker et al. disclose the claimed invention see col. 30-31 and figure 27C.

Regarding claims 18, 21, 23 and 25, Baker et al. disclose an electrosurgical device to treat tissue in a presence of radio frequency power (see for example col. 7, lines 9-14) and a fluid (see for example 450, i.e. saline) provided simultaneously from a distal portion of the device, the device having a proximal end and a distal end, the device and comprising: a handle (204 and alternate/equivalent counterparts in other embodiments); a shaft (100 and alternate/equivalent counterparts in other embodiments, see for example 578) extending from the handle, the shaft supporting an electrode (504 in figure 27A and 27B and 504 in figure 27C and 504 in the text) in rigid relation to the handle and having a

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distal end; a fluid passage (554 and/or 557) being connectable to a fluid source of the fluid (421 and alternate/equivalent counterparts in other embodiments); the electrode having an electrode surface, at least a portion of the electrode extending distally beyond the distal end of the shaft; the portion of the electrode extending distally beyond the distal end of the shaft comprising a neck portion and an enlarged end portion, the enlarged end portion located distal to the neck portion; and at least one fluid outlet opening in fluid communication with the fluid passage (distal openings of 554 and/or 557). Baker et al. also disclose a fluid passage (554 and/or 557) connectable to the fluid source and in communication with the at least one fluid opening to provide fluid from the source to the enlarged end portion of the electrode, see figures 27A-27C. Baker et al. fail to disclose the electrode and is an electrically conductive cone shaped portion having a circular portion that narrows towards the distal of the device. Eggers et al. disclose a device similar to that of Baker et al. and teach an embodiment wherein “the distal of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients

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generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel,” see col. 19:4-24 and figure 6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Baker et al., as taught by Eggers et al., to provide an embodiment wherein “the distal of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel.”



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Regarding claims 19, 20, 22, 24 and 26, Baker et al. disclose the claimed invention, see figures 27A-27C.

Regarding claims 40-45, Baker et al. disclose the claimed invention, see col. 23, lines 37-43, col. 30-31 and figures 27A-27C.

Regarding claim 47, Baker et al. disclose a surgical method for treating tissue comprising: providing tissue having a tissue surface; providing radio frequency power (see for example col. 7, lines 9-14) and a fluid (see for example 450, i.e. saline) to an electrosurgical device having a portion which simultaneously provides the radio frequency power and the fluid (entire reference) to a tissue treatment site, the portion comprising at least one fluid outlet opening (distal opening(s) of 554 and/or 557) and a distal end provided by an electrode; providing the fluid from the electrosurgical device; forming a localized fluid coupling with the fluid which couples the tissue surface and the electrode (entire reference), the fluid coupling localized at the portion of the electrosurgical device (see col. 30-31 and figure 27C.); providing the radio frequency power to the tissue (see for example col. 7, lines 9-14); moving the portion of the electrosurgical device along the tissue (inherent in dissection, cutting and/or removal); coagulating the tissue (see col. 9, line 44 through col. 10, line 6); and blunt dissecting the tissue (see col. 9, line 44 through col. 10, line 6) with the distal end of the electrosurgical device. Baker et al. fail to disclose the electrode and is an electrically conductive cone shaped portion having a circular portion that narrows towards the distal of the device.

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Eggers et al. disclose a device similar to that of Baker et al. and teach an embodiment wherein “the distal of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel,” see col. 19:4-24 and figure 6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Baker et al., as taught by Eggers et al., to provide an embodiment wherein “the distal of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the

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conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140).

With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel.”

Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent 6,149,620) in view of Eggers et al. (U.S. Patent 5,873,855) as applied to claim 10 above.

Regarding claim 13, Baker et al. disclose three equally spaced openings (see openings 54 with equally spaced ribs 96 of USPN 6,024,733 by incorporation by reference, see figure 9). Baker et al. fail to disclose 4 equally spaced openings/fluid outlets. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a fourth equally spaced rib that would subsequently provide four equally spaced openings, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

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Claim 46 rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent 6,149,620) in view of Eggers et al. (U.S. Patent 5,873,855) as applied to claim 47 above.

Regarding claim 46, Baker et al. in view of Eggers et al. disclose the claimed invention except for the cone shaped portion comprises an eccentric cone shaped portion. At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use an eccentric cone shape portion because Applicant has not disclosed an eccentric cone shape portion provides an advantage, is used for a particular purpose, or solves a stated problem for that of a concentric shape cone portion. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with concentric shape cone portion because they both provide the needed electrical conduction.

### ***Response to Arguments***

Applicant's arguments filed 04/26/2010 have been fully considered but they are not persuasive.

Regarding Applicant's arguments/remarks on page 10, next to last paragraph through page 11, 3<sup>rd</sup> full paragraph, the examiner could not more strongly disagree. It should be pointed out the collection of electrodes or the array of electrodes having a conical shape is interpreted broadly by the examiner as meeting the presently claimed electrode having a cone shaped

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surface, as there is nothing in the claim language to preclude this interpretation. Applicant may wish to further limit the claims in order to distinguish the presently claimed invention over that of the prior art combination and any possible interpretation of the prior art combination.

**The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.**

**This action is made FINAL.**

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771.

The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/  
Examiner, Art Unit 3769

/Henry M. Johnson, III/  
Supervisory Patent Examiner, Art Unit  
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